UpSwinG: Real World study on TKI activity in Uncommon mutations and Sequencing Giotrif®

First published: 10/03/2020

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Study Planned

Administrative details

EU PAS number

EUPAS32098

Study ID

32099

DARWIN EU® study

No

Study countries

Austria

China

France

Germany

Italy

Japan

Korea, Republic of

Spain

Taiwan

United Kingdom

Study description

This is a non-interventional, multi-country, multi-centre study based on existing data from medical records or electronic health records.The study observes how long patients with non-small cell lung cancer (NSCLC) benefit from treatment with Epidermal Growth Factor Tyrosine Kinase Inhibitor (EGFR-TKI) when given either for uncommon mutations or for common mutations in the sequence afatinib followed by osimertinib. Total enrolled: at least 200 patients per cohortFor both cohorts the study aims to describe the time on treatment until its end or death.

Study status

Planned

Research institutions and networks

Institutions

Royal Marsden Hospital

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Institution

Contact details

Study institution contact

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Primary lead investigator

Sanjay Popat

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/12/2019

Study start date

Planned: 09/12/2019

Data analysis start date

Planned: 01/12/2020

Date of final study report

Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim International

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

The study observes how long patients with non-small cell lung cancer (NSCLC) benefit from treatment with Epidermal Growth Factor Tyrosine Kinase Inhibitor (EGFR-TKI).

Main study objective:

The study aims to describe the time on treatment until its end or death.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, multi-country, multi-centre study based on existing data from medical records or electronic health records

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XE13) afatinib

afatinib

(L01XE02) gefitinib

gefitinib

(L01XE03) erlotinib

erlotinib

(L01XE35) osimertinib

osimertinib

Medical condition to be studied

Non-small cell lung cancer

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

400

Study design details

Outcomes

Time on treatment with EGFR-TKI(s), Overall survival, ORR, methodology and material used for mutational testing. Uncommon cohort only: time on treatment until failure of second line (TTF2).

Data analysis plan

The two cohorts will be analysed separately- Uncommon mutations- Sequencing of osimertinib after afatinibThe primary endpoint for both cohorts is time on treatment. Kaplan-Meier estimates will be calculated. In addition, the median will be tabulated along with the two-sided 95% confidence interval, using Greenwood’s variance estimate. The primary analysis will be repeated within subgroups. The following additional endpoints will be analyzed similarly to the primary endpoint.- overall survival- time on treatment until failure of second-line (uncommon cohort only)Patients who were not known to have discontinued treatment will be censored on the date they were last verified to have been on treatment.As an additional exploratory analysis, the data from the sequencing cohort of this study may be pooled with the previous GioTag study.

Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Retrospective patient-based data collection from patient's medical records

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No